REMARKS

Amendments to the Claims

Claim 4 is amended to recite that the polynucleotide component is polycistronic. Support is at page 44, lines 26-28. Claims 12, 13, 16, 30, 32, and 35 are amended to depend from claim 4. Claims 66 and 73 are amended to correct a clerical error. Claims 1-3, 9-11, 16-28, 80-82, and 90 are canceled.

The objection to now-canceled claim 82 for depending from a withdrawn claim is moot.

Rejection under 35 U.S.C. § 112 ¶ 2

The rejection of now-canceled claim 10 as indefinite is moot.

Rejection under 35 U.S.C. § 103(a)

There are four rejections for obviousness, each based on Barnett:[1]

- Claims 4, 7, 8, 12, 13, 32-34, 79, 84-86, 88, and 89 over Barnett in view of Aldovini,[2]
- Claims 13-15 over Barnett, Aldovini, and Corbet,[3]
- Claims 30 and 31 over Barnett, Aldovini, and Sailaja,[4] and
- Claim 87 over Barnett, Aldovini, and Surman.[5]

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[1] Barnett *et al.*, "Vaccination with HIV-1 gp120 DNA induces immune responses that are boosted by a recombinant gp120 protein subunit," Vaccine. 1997 Jun;15(8):869-73.

[2] U.S. Pat. No. 5,861,282.

[3] Corbet *et al.*, "Construction, biological activity, and immunogenicity of synthetic envelope DNA vaccines based on a primary, CCR5-tropic, early HIV type 1 isolate (BX08) with human codons," AIDS Res Hum Retroviruses. 2000 Dec 10;16(18):1997-2008.

[4] Sailaja *et al.*, "Long-term maintenance of gp120-specific immune responses by genetic vaccination with the HIV-1 envelope genes linked to the gene encoding Flt-3 ligand," J. Immunol. 2003 Mar 1;170(5):2496-507.

Barnett is cited as teaching a polynucleotide encoding an HIV Envelope protein. Office Action at page 6. The Patent Office acknowledges that Barnett does not disclose combining a plasmid with recombinant protein. Aldovini is cited as teaching particles containing Env proteins, mutating and deleting the gp160 cleavage site, and modifying HIV variable regions. Sailaja is cited as teaching adding a polypeptide antigen. Corbett is cited as teaching codon-optimized HIV envelope genes. Surman is cited as teaching removing glycosylation sites on HIV Env. The Patent Office contends that it would have been obvious to combine Barnett's polynucleotide with Aldovini's viral particles, and to modify the polypeptides according to the teachings of Corbett, Surman, and Sailaja.

To advance prosecution, independent claim 4 is amended to recite that the polynucleotide component is a polycistronic polynucleotide. The remaining claims depend from claim 4. Applicants traverse the rejections as applied to the amended claims.

To make a *prima facie* case of obviousness, an examiner must make "a searching comparison of the claimed invention—including all its limitations—with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, C.C.P.A. 1974).

Barnett does not teach or suggest a polycistronic polynucleotide encoding more than one HIV protein. Rather, Barnett teaches and suggests only plasmids encoding only one HIV protein. For example, figure 1, on page 870, col. 2, shows plasmids encoding one Env protein from each of HIV strains SF2, US4, or CM235.

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[5] Surman *et al.*, "Localization of CD4+ T cell epitope hotspots to exposed strands of HIV envelope glycoprotein suggests structural influences on antigen processing," Proc Natl Acad Sci U S A. 2001 Apr 10;98(8):4587-92.

None of Aldovini, Corbet, Sailaja, and Surman, alone or in combination, cures the deficiencies of Barnett described above. Aldovini teaches replacing wild-type Env genes with different Env strains, but does not teach or suggest a polynucleotide encoding more than one Env protein. Rather, Aldovini's direction to immunize with multiple Env proteins is limited to "combining HIV particles containing a spectrum of various Env proteins for wider protection." Col. 7, lines 47-50. Nothing in Corbet, Sailaja or Surman teaches or suggests any combination of multiple HIV-encoding polynucleotides, let alone a polycistronic polynucleotide comprising two coding sequences for two HIV immunogenic polypeptides.

The Patent Office has not made a *prima facie* case of obviousness. Please withdraw the rejections.

Respectfully submitted,

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Dated: September 14, 2010

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